

### Remarks/Arguments

Reconsideration of this Application and entry of this Amendment are respectfully requested. Claims 1-9 are pending in this application and claims 10-22 are withdrawn as the result of a restriction requirement. Claims 1-8 stand rejected under 35 U.S.C. §102 and claim 9 stands rejected under 35 U.S.C. §103(a).

#### Rejections under 35 U.S.C. §102

Claims 1-3, 7-8 have been rejected under 35 U.S.C. §102(b) as being anticipated by DE4028622 (the '622 patent); claims 1-4 and 7-8 are rejected under 35 U.S.C. §102(a) as being anticipated by RU 2176511 C1 (the '511 patent) and claims 1-8 are rejected under 35 U.S.C. §102(e) as being anticipated by United States Patent No. 6,821,264 (the '264 patent).

Claims 1-3 and 7-8 have been rejected under 35 U.S.C. §102(b) as being anticipated by DE4028622 (the '622 patent). According to MPEP 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." The Examiner states in the Office Action of April 27, 2005 that "'622 disclose the preparation of a Porifera-derived product, collagen sponges (abstract)." Applicant has obtained a certified translation of the '622 patent, a copy of which is enclosed with this response. Applicants respectfully assert that the '622 patent does not disclose a Porifera-derived product, it discloses sponges made from collagen materials. The '622 patent is completely unrelated to the present application. The word "sponge" occurs in the title of the '622 patent as a description of a collagen composition having the structure of a sponge. The '622 patent describes methods for producing foam-like structures (sponges) from bovine or porcine collagen. The '622 patent does not disclose or claim naturally occurring sponges of the species *Spongilla lacustris* L., *Spongilla fragilis* Leidy or *Ephydatia fluviatilis* which are the subject matter of the present application. Collagen is, in fact, a structural protein found in animals and is not Porifera-derived.

Therefore claims 1-3 and 7-8 are not anticipated by the '622 patent because the '622 patent does not describe, either expressly or inherently, Porifera-derived products. Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. §102(b) of claims 1-3 and 7-8 and pass these claims to allowance.

Claims 1-4 and 7-8 have been rejected under 35 U.S.C. §102(a) as being anticipated by RU 2176511 C1 (the '511 patent). The Examiner has stated that the '511 patent "disclose a dermatological composition comprising a Porifera-derived material, a fresh-water sponge of the *Spongillidae* family, and ethyl alcohol, a pharmaceutically acceptable excipient (abstract)." Applicant respectfully disagrees that the '511 patent discloses the invention of the instant application.

The '511 patent discloses "...the agent consisting of a 40-70% an aqueous-spirituous tincture (extract) of fresh-water sponge of *Spongillidae*." The Porifera-based composition of the instant application comprises a substantially pure powder of Porifera sp., wherein the powder is made from the entire Porifera sp. organism which has been separated from environmental debris, washed, dried, ground, sieved and sized (paragraph 0085). The Porifera-based composition of the instant application comprises the entire organism, including all biologically active molecules found therein, rather than a water/ethanol extract which only contains a subset of the biologically active molecules found in the organism. The '511 patent actually teaches away from claims 1-4 and 7-8 of the instant application in that it requires an extraction of shredded sponge with 40-70% ethanol in water for 20-40 days in order to prepare the disclosed composition.

Claim 1 has been amended to further define the subject matter of Applicant's invention as a "substantially pure powder of a Porifera sp." Support for this claim amendment is found in the specification in paragraph 0085.

In order for a reference to anticipate a claim under 35 U.S.C. §102(a), each and every element as set forth in the claim must be found, either expressly or inherently, in a single prior art reference. The '511 patent does not disclose, either expressly or inherently, a Porifera-based product wherein the product comprises a substantially pure powder of a Porifera sp., as does amended claim 1. Therefore, claim 1 is not

anticipated by the '511 patent. Additionally, as amended independent claim 1 is not anticipated by the '511 patent, dependent claims 2-4 and 7-8 are therefore also not anticipated by the '511 patent. Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. §102(a) of claims 1-4 and 7-8 and pass these claims to allowance.

Claims 1-8 have been rejected under 35 U.S.C. §102(e) as being anticipated by United States Patent No. 6,821,264 (the '264 patent). The Examiner has stated that the '264 patent "disclose a gene-delivery device for applying a pharmaceutical composition to a contact surface, such as a tissue site (abstract). In one embodiment, the contact surface comprises a Porifera-derived material, a sponge material (column 10, lines 49-54)." Applicant respectfully disagrees that the '264 patent discloses the invention of the instant application.

The '264 patent discloses "[a] gene delivery device for localizing and enhancing the efficacy of gene transfer that provides a contact surface for contacting with a tissue site" (abstract). The contact surface is defined as "comprising a plurality of contact elements, such as bristles, fibers, the protrusions of a sponge, prongs, tines and the like" (column 4 lines 24-27). The '264 patent further states "[i]n one embodiment of the invention, the contact surface is a porous material, such as a sponge." (column 5 lines 3-4). The '264 patent discloses using a sponge solely as an applicator for therapeutic compositions, including gene therapy agents. The '264 patent does not disclose the sponge itself as a therapeutic composition.

In order for a reference to anticipate a claim under 35 U.S.C. §102(e), each and every element as set forth in the claim must be found, either expressly or inherently, in a single prior art reference. The '264 patent does not disclose, either expressly or inherently, a Porifera-based product wherein the product comprises a substantially pure powder of a Porifera sp., as does amended claim 1. Therefore, claim 1 is not anticipated by the '264 patent. Additionally, as amended independent claim 1 is not anticipated by the '264 patent, dependent claims 2-8 are therefore also not anticipated by the '264 patent. Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. §102(e) of claims 1-8 and pass these claims to allowance.

Therefore Applicant respectfully asserts that, based on the arguments submitted *supra*, that claims 1-8 of the present application are allowable and requests that the rejections under 35 U.S.C. §§102(a), (b) and (e) be withdrawn.

Rejections under 35 U.S.C. §103(a)

Claim 9 has been rejected under 35 U.S.C. §103(a) as being unpatentable over 2176511 C1 (the '511 patent ) in view of U.S. Patent No. 3,896,238 (the '238 patent).

The Examiner has stated that the '511 patent "disclose a dermatological composition comprising a Porifera-derived material, a fresh-water sponge of the *Spongillidae* family, and ethyl alcohol, a pharmaceutically acceptable excipient (abstract)." Applicant respectfully disagrees that the '511 patent discloses the invention of the instant application.

The '511 patent discloses "...the agent consisting of a 40-70% an aqueous-spirituous tincture (extract) of fresh-water sponge of *Spongillidae*." The Porifera-based composition of the instant application comprises a substantially pure powder of Porifera sp., wherein the powder is made from the entire Porifera sp. organism which has been separated from environmental debris, washed, dried, ground, sieved and sized (paragraph 0085). The Porifera-based composition of the instant application comprises the entire organism, including all biologically active molecules found therein, rather than a water/ethanol extract which only contains a subset of the biologically active molecules found in the organism. The '511 patent actually teaches away from claims 1-4 and 7-8 of the instant application in that it requires an extraction of shredded sponge with 40-70% ethanol in water for 20-40 days in order to prepare the claimed composition.

Claim 1 has been amended to further define the subject matter of Applicant's invention as a "substantially pure powder of a Porifera sp."

Regarding the '238 patent, the Examiner stated that the '238 patent discloses "an anti-acne composition and kit for packaging said composition (column 23, lines 2-65)....Therefore it would have been obvious to one of ordinary skill in the art at the time

the invention was made to package an anti-acne composition, such as the one advanced the instant application, in a kit."

In order to establish a prima facie case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The combination of the '511 patent and the '283 patent do not teach or suggest all the claim limitations. The combined references fail to teach all the limitations of claim 9 which include "[a] composition for treating skin diseases comprising a Porifera-derived product made in accordance with Good Manufacturing Practices (GMP) wherein said Porifera-derived product comprises a substantially pure powder of a Porifera sp." The '511 patent discloses an agent consisting of a 40-70% aqueous-spirituos tincture (extract) of shredded fresh-water sponge of the family Spongillidae, not a substantially pure powder of a Porifera sp. The '238 patent does not disclose Porifera-based products. Therefore the combination of the '511 patent and the '283 patent do not teach or suggest all the claim limitations of claim 9.

Applicant respectfully asserts that claim 9 of the present application is allowable and requests that the rejection under 35 U.S.C. §103(a) be withdrawn.

### **Conclusion**

Claims 1-9 and 23-25 are pending in the instant application. Claim 1 has been amended and new claims 23-25 have been added.

For the foregoing reasons, Applicant believes pending claims 1-9 are in condition for allowance and should be passed to issue. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call Louis C. Cullman at 949-253-0900.

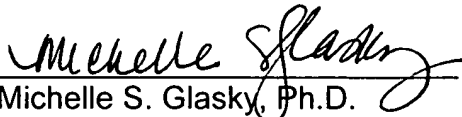
Application No.: 10/659,451  
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Applicant: Maria Villani

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The Commissioner is authorized to charge any fee which may be required in connection with this Notice or credit any overpayment to deposit account No. 50-3207.

Respectfully submitted,

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